IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:	
Meir Rosenberg	
Application No.: 10/607,121	Confirmation No.: 5583
Filed: June 26, 2003	Art Unit: 3761
For: SELF ADJUSTING HYDROCEPHALUS VALVE	Examiner: Leslie R. Deak

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Dated: May 5, 2006 Signature _____ (Charlton Shen)

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AMENDMENT AND RESPONSE TO ADVISORY ACTION AND REQUEST FOR CONTINUED EXAMINATION

Dear Sir/Madam:

This communication is in response to the Advisory Action dated March 29, 2006, and the Final Office Action dated January 11, 2006. The paper is being submitted concurrently with a Request for Continued Examination. Please amend the above-identified U.S. patent application as follows:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 5 of this paper.

AMENDMENTS TO THE CLAIMS

1. (Currently Amended) A self adjusting hydrocephalus valve for regulating cerebrospinal fluid in a patient, comprising:

a housing enclosing therein a chamber that is able to permit fluid flow therethrough,

an inlet port in fluid communication with the chamber to accommodate passage of fluid into the chamber, and an outlet port in fluid communication with the chamber to accommodate passage of fluid out of the chamber; and

a valve mechanism disposed within the housing for regulating the rate of fluid flow through the chamber, the valve mechanism including a valve seat adjacent to an opening in the inlet port, a blocking member configured to seat in the valve seat, and a biasing element for exerting a biasing force against the blocking member to selectively maintain the blocking member against the valve seat and prevent fluid flow therethrough, the biasing element being configured to respond to a pressure difference within the valve;

wherein the biasing element has ~~an adjustable~~ a self-adjusting, damped resistance to allow fluid release at a rate which is proportional to an average pressure difference over time.

2. (Original) The valve of claim 1, wherein the biasing element is connected to the blocking member.

3. (Original) The valve of claim 1, wherein the biasing element comprises a spring element.

4. (Original) The valve of claim 1, wherein the biasing element comprises at least one flexible bellows defined by a base plate, an opposed end plate, and a collapsible side wall extending therebetween.

5. (Original) The valve of claim 4, wherein the biasing element comprises a single flexible bellows.

6. (Original) The valve of claim 5, wherein the end plate connects to a support member for securing the biasing element to the housing.

7. (Original) The valve of claim 5, wherein the support member includes apertures permitting fluid flow therethrough.

8. (Original) The valve of claim 4, wherein the at least one flexible bellows is formed from a biocompatible elastomeric material.

9. (Original) The valve of claim 5, wherein the end plate of the single flexible bellows includes an orifice to provide fluid communication between the single flexible bellows and the chamber.

10. (Previously Presented) The valve of claim 4, wherein the biasing element comprises two flexible bellows, the first flexible bellows being sequentially connected to the second flexible bellows.

11. (Original) The valve of claim 10, wherein the first and second bellows are connected by an orifice such that the first flexible bellows is in fluid communication with the second flexible bellows.

12. (Original) The valve of claim 11, further including a support member extending between the first and second flexible bellows for securing the biasing element to the housing.

13. (Previously Presented) The valve of claim 12, wherein the support member includes apertures permitting fluid flow therethrough.

14. (Previously Presented) The valve of claim 10, wherein the first and second bellows form a closed fluidic system.

15. (Original) The valve of claim 13, wherein the first flexible bellows is connected to the blocking member.

16. (Original) The valve of claim 13, wherein the first and second flexible bellows are formed from a biocompatible elastomeric material.

17. (Original) The valve of claim 13, wherein the biasing element is at least partially filled with a fluid.

18. (Original) The valve of claim 17, wherein the fluid is an inert gas.

19. (Original) The valve of claim 1, wherein the blocking member is a spherical ball.

20. (Currently amended) The valve of claim [[24]] 19, wherein the valve seat has a spherical surface for mating with a portion of an outer surface of the spherical ball.

21. (Previously Presented) The valve of claim 1, wherein the biasing element is configured to accommodate passage of fluid from the inlet port to the chamber without passage through the biasing element.

REMARKS

Status of the Claims

Claims 1-21, as amended by Applicant's paper dated November 11, 2005, are pending in this application. Claims 1 and 20 are amended. Reconsideration of the pending claims is respectfully requested.

Telephone Interview of April 13, 2006

Applicant's representative, Charlton Shen, thanks the Examiner for the courtesies extended during the telephone interview of April 13, 2006, with Examiner Leslie Deak. During the telephone interview, cited art references U.S. Patent No. 5,810,761 and U.S. Patent No. 5,935,084 were discussed with respect to (i) the present application, and (ii) pending claims 1, 21, and 22 as amended in the response to the Final Office Action filed by the Applicant on March 13, 2006.

Amendments to the Claims

Claim 1 is amended to recite that "the biasing element has a *self-adjusting, damped* resistance to allow fluid release at a rate which is proportional to an average pressure difference over time." Support for the amendment is found in the published application at paragraph [0029] (explaining that "[w]hen CSF force acts on the blocking member 46...the biasing element 50 adjusts according to the pressure exerted on the blocking member 46," and describing a biasing element that acts as a damper). As such, the amendment does not add new matter.

Claim 20 is also amended to depend from claim 19, correcting a typographical error. As such, the amendment does not add new matter.

Novelty

Claims 1-9 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,810,761 to Saens-Arrollo (herein "Saens-Arrollo"). The claims, however, are novel because Saens-Arrollo fails to teach a biasing element in a hydrocephalus valve that has a *self-adjusting, damped* resistance to allow fluid release at a rate which is proportional to an average pressure difference over time.

Amended independent claim 1 is drawn to a self adjusting hydrocephalus valve for regulating cerebrospinal fluid. The claim recites, *inter alia*, a valve mechanism having a biasing element for exerting a biasing force against the blocking member to selectively maintain the blocking element against the valve seat. In particular, the biasing element "has *self-adjusting, damped resistance* to allow fluid release at a rate which is proportional to an average pressure difference over time." One example of the response of a valve mechanism having a self-adjusting, damped resistance is depicted in FIG. 5, and described in corresponding paragraph [0034], of the present application. As depicted in FIG. 5, the resistance of the valve self-adjusts with a damped response in time to the average pressure change; the resistance is not constant, nor does it change instantaneously with the instantaneous changes in pressure.

In contrast, Saens-Arrollo provides no teaching or suggestion of a biasing element having a *self-adjusting, damped* resistance. First, the pressure control valve in Saens-Arrollo's pressure control device is not self-adjusting. The patent specifically states that the resistance of the valve "is mainly determined by the [pressure control] device . . . which is *set* to open and close within the *specifically preset* pressure range" (see Saens-Arrollo, column 2, lines 12-15, emphasis added). That is, the resistance of the pressure control device is *predefined* by a *user-chosen* configuration. There is no mention of a biasing element that has an *self-adjusting* resistance as recited in amended claim 1. Accordingly, the Examiner's observation that Saens-Arrollo reveals "a valve that may be set to open at varying pressures" (see item 6 of the Final Office Action) does not teach or suggest a valve biasing element having a *self-adjusting* resistance.

Second, Saens-Arrollo fails to provide any teaching or suggestion of a biasing element having a *damped* resistance. In contradistinction, Saens-Arrollo teaches a valve control device having a *constant* resistance that allows fluid release at a rate proportional to the *instantaneous* pressure difference. As described in Saens-Arrollo at column 2, lines 8-15,

> "[t]he flow (F) passing through the equipment is set by the difference in pressure (dP). . . and the resistance (R) thereof . . . wherein F = dP/R. The resistance of the equipment is mainly *determined* by the device integrated to the pressure control valve . . ." (emphasis added).

That is, the resistance is *constant*, and therefore the fluid flow is proportional to the *instantaneous* pressure drop. Such a teaching contrasts sharply with the recitation of amended

claim 1, in which the biasing element has a *damped* resistance. Indeed, plotting a graph similar to FIG. 5 of the present application for the Saens-Arrollo valve would result in a pressure graph that would track with the instantaneous pressure, and the resistance would be a flat horizontal line. Accordingly, the structural features of the Saens-Arrollo valve do not reveal the recitations of amended claim 1. As such, the recitation of claim 1 is not merely "a recitation of intended use."

Accordingly, Saens-Arrollo provides no teaching or suggestion of a biasing element having "a self-adjusting, damped resistance to allow fluid release at a rate which is proportional to an average pressure difference over time." For these reasons, among other, claim 1 not anticipated by the reference. Claims 2-9 depend from claim 1, and are not anticipated for substantially the same reasons, among others. For example, as discussed in the previous response, claims 6 and 7 are distinguished from Saens-Arrollo since the reference does not teach a valve having an end plate connected to a support member (claim 6), or a support member that includes apertures permitting fluid flow therethrough (claim 7).

Claims 1-9 are clearly novel.

Nonobviousness

Claims 10-21 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Saens-Arrollo in view of U.S. Patent No. 5,935,084 to Southworth (herein "Southworth"). The claims, however, are not obvious because, *inter alia*, the references do not teach all the recitations of amended, independent claim 1, from which the claims depend.

As discussed above, Saens-Arrollo does not anticipate amended claim 1 because it fails to teach the recitations of the claim, i.e., a valve mechanism including a biasing element having a self-adjusting, damped resistance to allow fluid release at a rate which is proportional to an average pressure difference over time. Southworth also provides no teaching of a self-adjusting hydrocephalus valve with a biasing element having a self-adjusting, damped resistance. Indeed, the reference is drawn to a completely different mechanism: a pressure indicator having a fluid-filled bellows for making pressure measurements. There is absolutely no hint, suggestion, or motivation (i) that the bellows provides damped resistance; and (ii) to use the fluid-filled bellows of Southworth to replace the valve control device in Saens-Arrollo whatsoever. Indeed,

Southworth teaches away from amended claim 1 by suggesting that shunt systems' threshold pressures are manipulated by a surgeon who can "initially select a...threshold pressure" (see Southworth, column 1, line 66 to column 2, line 1). That is, the reference only discusses manually adjusted shunt systems – there is no teaching of self-adjustment. The only way amended claim 1 is achieved is through the teachings of the present application. Thus, the cited art can only render amended claim 1 obvious with the use of impermissible hindsight.

Furthermore, combining the fluid-filled bellows of Southworth with the valve of Saens-Arrollo renders the valve inoperable. As shown in FIGS. 2 and 3 of Saens-Arrollo, the pressure control bellows (C) has perforations (K) to allow fluid to flow through the bellows. If the pressure control bellows is replaced with the fluid-filled bellows of Southworth, the replacement would render the Saens-Arrollo valve unworkable since fluid would not have a passageway to flow through. To puncture the fluid-filled bellows would completely change the operation of the bellows since it is the closed fluid system that provides the pressure response device of Southworth. Only the present application provides the disclosure necessary to combine the elements of Saens-Arrollo and Southworth to practice the pending claims. For example, the subject matter of claim 21, wherein fluid passage does not occur through the biasing element, is supported by the embodiment shown in FIG. 3 of the application and the corresponding discussion at paragraph [0029] of the published application.

Accordingly, the combination of Saens-Arrollo and Southworth cannot render amended claim 1 obvious. Since claims 10-21 also depend from amended claim 1, the claims are also not obvious for at least the same reasons. As such, Saens-Arrollo cannot render claims 10-18 obvious under this rationale. The claims are also patentable for other reasons. For example, the cited art does not disclose a support member between two bellows (claim 12), and/or a support member including apertures permitting fluid flow therethrough (claim 13). Nor does the cited art teach or suggest a first and second bellows forming a closed fluidic system as recited in claim 14. Claim 21 also represents patentable subject matter since the cited art provides no teaching or suggestion of a biasing element configured to accommodate fluid passage without passage through the biasing element.

It is finally noted that claims 10-18, which depend from claim 1 and include a recitation for two flexible bellows, cannot be "a mere duplication of the working parts of a device found in

the prior art," as stated in the Office Action. for the reasons stated above (i.e., the novelty and nonobviousness of amended claim 1). Contrary to the suggestion in the Office Action that "the second bellows does not appear to cause a different mode of operation," one embodiment is shown in FIG. 3, and described at paragraph [0029] of the published application, that utilizes changes in volumes of the two bellows to cause the biasing element to act as a damper or shock absorber. As such, the two bellows are not a "mere duplication of working parts."

CONCLUSION

In view of the remarks above, Applicant submits that claims 1-21 are in condition for allowance, and allowance thereof is respectfully requested. Applicant encourages the Examiner to telephone the undersigned in the event that such communication might expedite prosecution of this matter.

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Respectfully submitted,

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